MDDAP 2018

What did we set out to do with the pilot in 2018?
What did we accomplish?
Are we on track?
Where do we go in 2019?
## Case for Quality: Original Work Streams

### Original Work Streams Overview

#### Case for Quality Competency Working Group
The purpose of this project was to improve medical device Quality by improving overall competency, awareness, and understanding across key stakeholders that have the most influence on device Quality. *Completed in 2016.*

#### Medical Device Quality Metrics Initiative
To provide a system of metrics across the Total Product Lifecycle that enables companies to assess and improve the robustness of their critical-to-quality practices, and therefore, risk to product quality. Identification of quality system metrics that will inform decisions and trigger action in a way that shifts the Right-First-Time mentality closer to the initial days of development. *Final report out June 2016.*

#### Case for Quality Advanced Analytics
Development of an analytics dashboard to use accessible quality data to inform a user-friendly dashboard make it possible to make informed decisions about the use of a device based on quality. Such a dashboard makes it possible for medical device companies to effectively demonstrate the quality of their products. This dashboard also has the potential for physicians, patients, hospitals and the FDA to visualize quality data in near real-time, as the dashboard will be populated using EHR and registry data. *Ongoing.*

#### MDIC Maturity Model Work Stream
*Commissioned October 2014*
Focused on adapting the CMMI process framework to medical devices then developing content for the selected process areas. A proof-of-concept to understand at a high-level if the applicability of the CMMI model consistently across an industry is feasible, identify any issues with assessors/industry/FDA, and develop a plan for the full scale deployment. *Launched as part of the CDRH pilot in 2017*
Pilot program

- 3rd-party maturity appraisal that leverages the Capability Maturity Model Integration (CMMI) framework to assess a medical device organization’s capability to produce high-quality devices and increase patient safety
  - Quarterly progress check with lead appraiser
  - Quarterly metrics/KPI submission to FDA
- Pilot was announced on December 28, 2017 and will run from January 2, 2018 and continue through December 28, 2018

FDA adjustments

- Forgo surveillance, post-approval, and risk-based inspections
- Manufacturing change notice submissions
  - Streamlined submission
  - Accelerated acceptance 5 business days vs. 30 days
- Manufacturing site changes
  - Streamlined submission
  - Accelerated approval – 10 business days
- Original PMA manufacturing section
  - Streamlined submission
  - Forgo preapproval inspection
Current Governance Structure

Bi-Monthly Alignment Meeting with MDIC, FDA, and the CMMI Institute PMO to:
- Review the current state of the program, relevant metrics, and results;
- Discuss connection points with industry;
- Make decisions; and
- Address lessons learned and next steps in program;

Bi-Monthly Appraiser Meetings with the Institute to discuss:
- Scheduling and coordinating upcoming appraisals;
- Review evolving program activities and expectations; and
- Discuss lessons learned to improve appraisal best practices for MDDAP.

Monthly Participant Meetings with all participants in the program (representatives), the Institute (PMO), MDIC, and FDA (CDRH). These meetings are focused on:
- Reviewing the program, relevant metrics, and results;
- Discussing connection points between FDA and industry (e.g. benefits); and
- Addressing next steps in program.

As necessary, working groups are created from this larger group to address any specific concern, issue, or topic requiring attention.
Current Governance Structure

Quarterly MDICx webinars with the public to provide a broad update from:
  MDIC;
  FDA;
  Institute PMO; and
  Industry participants regarding their experiences.

Case for Quality Forums (quarterly or as needed) with the public to:
  Gather input and feedback; and
  Share the latest updates, lessons learned, and next steps.

Steering Committee Meeting (quarterly or as needed) to:
  Receive guidance from the committee; and
  provide or discuss the latest updates, lessons learned, and next steps.
What Does Success Look Like?

Success Components

**Consistency & Scalability**
Is the program sustainable?
“Program Adoption”

**Value to Participants**
What value are stakeholders getting from program?
“Program Effectiveness”

**Elevating Industry**
The long term “next steps”...

Success Identification

**What**: Program operations are performed consistently for growing # new participants

**How**: Number of participants enrolled, number of appraisals, wait time to appraisal, number of appraisers trained in the program, lessons learned incorporated into program*

**What**: Appraisal identifies opportunities for improvement, reduced regulatory burden, increased innovation, faster time to market

**How**: Survey results, participant feedback, appraiser feedback, FDA feedback, lessons learned incorporated into program*

**What**: Industry baseline for organizations to measure improvement journey

**How**: trend participant results & quality performance metrics over time
Are we on track?
Program Adoption

Facilities Enrolled:
40 over 18 Companies

Appraisals Executed:
28 all time, 22 YTD
  Appraisals Scheduled: 6
  Appraisals being scoped: 1

Time from Enrollment to Appraisal:
110 days

Appraisers in program:
11 current, 16 pending

Trained Embedded ATMs:
27 participants, 9 FDA
# Program Effectiveness

## Current Pilot Statistics

- 40 Enrolled sites
  - 36 Active Sites/18 Companies
  - 4 Multi-site appraisals (Appraisal where the whole value stream is evaluated, not just the specific site performance)
- 14% are FDA recognized small businesses
- Class I Only Sites: 1
- Class II Only Sites: 6
- Class III Only Sites: 3
- Class I and Class II Sites: 6
- Class I and Class III Sites: 0
- Class II and Class III Sites: 13
- All Class Products at Site: 7

## CDRH Metrics

- 38 Modified change notices reviewed
- 35 Reviewed in 5 days or less
  - Average review time (2.8 days)
  - **One reviewed in 13hr**
- 1 Reviewed in 10 days with 7 changes in one submission
- 2 Converted to traditional 30-Day
  - 1 had drug-component change that required CDER consult
  - 1 site was not yet approved for the modifications

## Inspection Metrics

- Routine Inspections Waived: 40
- Pre-Approval Inspections Waived: 4
- For causes that occurred: 3
  - No observations
- Foreign sites: 9

## Site transfer

Streamlined template developed by ODE reviewers. 2 participants ready to test
**Program Effectiveness**

Post-Appraisal Survey Results:
(158 respondents)

Experience with appraisal
positive: 92.4%
neutral: 7.6%
negative: 0%

Value to product quality
yes: 85.4%

Conflict with compliance
no: 98.1%

Appraisal has value add
yes: 94.3%

Would recommend pilot
yes: 99.4%

“The maturity assessment provided us with an evaluation of the health of our operations, engaging individuals most familiar with our day-to-day work. The assessment helped us identify strengths and weaknesses and opportunities for further consideration.

As important, the assessment helped us develop operational excellence metrics that will measure the continuous execution and quality oversight of our processes. Now, a cross-functional team is exploring how we can capitalize on what we learned to further advance our processes and our ability to provide world-class products and services to our customers.”

Kathie Bardwell
SVP & Chief Compliance Officer
STERIS Corporation
Participant Comments

• The objectives were clearly defined and the meetings and line of questions were well-organized.

• CMMI Consultants were knowledgeable and great to work with.

• Every effort was made to put me at ease and help me understand the process.

• I felt 90% of the appraisal results resonated with me and what I know about our organization. That's a pretty good success rate for such a short time with us.

• The majority of weaknesses identified during the process highlight legitimate areas for improvement.

• A huge leap forward in identifying the issues that hold back a compliant, high-performing company.

• The overall approach, if supported, genuinely will be more effective than the reactionary approach to traditional inspections.
Where do we go in 2019?
2019 Considerations

Scaling
• Appraisers (ATLs/Embedded ATMs)
• Participants & Appraisals

Expanding
• Regulatory Modifications
• Performance Report
  • Linking capability to product quality
  • Improvement beyond an appraisal

Adjusting
• Multi-site appraisals
• Reappraisal tailoring for value add
  • Practice areas, practices, capability levels

Exploring
• Low to non-compliant organizations
2019 Risks

Operational
• Scaling to meet demand
• Avoiding a compliance model

Adoption
• Cost effectiveness
• Participant struggles

Unplanned
• Participant compliance issue
• Attempts to ‘game the system’
Your Involvement...
Additional Information

General Information:
http://cmmiinstitute.com/MedicalDevice

Resources:
2017 Nov 15: MDIC Meeting Presentation
2017 Oct 10: FDA Public Meeting Presentation
2018 Feb 27: Q1 MDICx Webinar and Slides
2018 May 7: Medtech's Next Top Maturity Model: Part 1
2018 May 8: Medtech’s Next Top Maturity Model: Part 2
2018 June 5: Q2 MDICx Webinar and Slides
2018 June 25: Medtech’s Next Top Maturity Model: Part 3
2018 June 27: MDIC Case for Quality Open Forum
2018 July 11: Greenlight Guru Case for Quality Webinar with Cisco: Part 1
2018 Aug 16: Greenlight Guru Case for Quality Webinar with Cisco: Part 2
2018 Sept 5: MDIC Annual Public Forum
2018 Sept 12: Q3 MDICx Webinar
2018 Sept 20: Medtech’s Next Top Maturity Model: Part 4
2018 Sept 20: Greenlight Guru Case for Quality Webinar with Cisco: Part 3
2018 Dec 6: Q4 MDICx Webinar